REMARKS

Applicants have canceled claims 1-7, 12-23, 27-28, and 32-33. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the cancelled claim in this or any other patent application. Claims 10-11, 24-26, 29-31, and 34-35 are withdrawn.

Applicants have amended claims 8 and 36 to recite "a sustained release formulation of a weight loss affecting amount of." Support for these amendments can be found throughout the specification, including the claims as originally filed, for example, at ¶¶0085, 0100, 0102, 0150, 0205, and 0219 of the specification. Applicants have also added new dependent claims 38-43 wherein the amount of naltrexone is 5-50 mg and/or the amount of bupropion is 30-300 mg. Support for these claims can be found, for example, at ¶0220 of the specification. New claims 38-42 fall within the elected species. New claims 44 and 45 recite "wherein the second compound further comprises zonisamide." Support for this amendment can be found, for example, at ¶¶0034-35. New claims 44 and 45 are directed to unelected species, but are dependent from the pending genus claims 8 and 36 respectively, and therefore should be allowed if the genus claims are deemed allowable. Support for new claims 46 and 47 can be found, for example, at ¶219. Support for new claims 48-49 can be found, for example, at ¶¶0088-89. New claims 46-49 fall within the elected species.

Claim Objections

The PTO objects to claims 8 and 36 because "the claims include the species **prodrug** which is not directed to the elected species." *Office Action* at 2. The PTO requires appropriate correction. Applicants respectfully submit that no correction is required.

In the previous Office Action, mailed July 27, 2006, the PTO required restriction to one of the following groups:

> Group I: Claims 8-9 and 36-37, drawn to compositions related to naltrexone and bupropion, classified in class 514, subclass 282 and 657.
>
> Group II: Claims 10-11, 19 and 22-35, drawn to a methods of using compositions related to naltrexone and bupropion for weight loss, classified in class 514, subclass 282 and 657.

In response, Applicants elected Group I, Claims 8-9 and 36-37. Upon election of Group I, the PTO required election of one of the following species of Group I:

(A) naltrexone as the 1st compound and bupropion as the 2nd compound
(B) a prodrug of naltrexone as the 1st compound and bupropion as the 2nd compound
(C) naltrexone as the 1st compound and a prodrug of bupropion as the 2nd compound
(D) a prodrug of naltrexone as the 1st compound and a prodrug of bupropion as the 2nd compound.

In response, Applicants have elected species (A), naltrexone as the 1st compound and bupropion as the 2nd compound, without traverse, for further prosecution on the merits, with the understanding that Applicants will be entitled to consideration of claims to additional species upon allowance of a generic claim. Applicants stated that claims 8-9 and 36-37 read on the elected species.

It is Applicants understanding that there is no need to cancel or amend genus claims such as claims 8 and 36 as a result of electing species (A). *See 37 C.F.R. § 1.141* ("Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.") (emphasis added); *see also 37 C.F.R. § 1.146* ("...the examiner may require the applicant ...to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.") (emphasis added). Applicants understand that the PTO should examine claims 8 and 36, and determine if Applicants are entitled to genus claims 8 and 36 as presented. Only if no claim to the genus is found to be allowable will Applicants be restricted to the elected species. If Applicants understanding of the rules regarding election of species is incorrect, Applicants invite the Examiner to contact the undersigned to discuss corrective actions to be taken.

35 U.S.C. § 102(b) - Anticipation

The PTO has rejected claims 8-9 and 36-37 under 35 U.S.C. § 102(b) as being anticipated by Dante (US Patent 5,817,665). The PTO asserts that Dante discloses a composition for treating depression comprising a pharmacologically effective does of a compound of opioid antagonists and a pharmacologically effective dose of a compound of nontricyclic antidepressants. The PTO also asserts that the opioid antagonist can be naltrexone (claim 9, line 5) and the nontricyclic antidepressant can be bupropion (claim 12, line 4). Therefore, the PTO concludes that a composition or a pharmaceutical composition of naltrexone and bupropion is clearly anticipated.

Applicants respectfully submit that Dante does not anticipate pending claims 8-9 and 36-37. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Claim 8 recites:

> A composition for affecting weight loss comprising a sustained release formulation of a weight loss affecting amount of a first compound and a second compound, wherein said first compound is naltrexone, or a pharmaceutically acceptable salt or prodrug thereof, and said second compound comprises bupropion, or a pharmaceutically acceptable salt or prodrug thereof.

Applicants respectfully submit that Dante does not disclose a composition comprising a sustained release formulation of a weight loss affecting amount of naltrexone and bupropion, (or their pharmaceutically acceptable salts or prodrugs). Likewise, Dante does not disclose the pharmaceutical composition of claim 36, which also recites a sustained release formulation of a weight loss affecting amount of naltrexone and bupropion (and their pharmaceutically acceptable salts or prodrugs). As such, Dante does not anticipate pending claims 8 or 36, or any of dependent claims 9, or 37-45, which depend therefrom.

In addition, Applicants note that the combination of naltrexone and bupropion appears to have unexpected properties, making the combined composition non-obvious. Applicants direct the Examiner's attention to Example 8, hours 2 and 4 of the instant application. In addition, pursuant to 37 C.F.R. § 1.132, Applicants submit herewith as Exhibit 1 a declaration of Michael A. Cowley, Ph.D., an expert in the field and co-inventor of the instant application. As Dr.

Cowley's declaration states, the combination of naltrexone and bupropion has unexpected, non-obvious properties.

CONCLUSION

In view of the above, Applicants respectfully maintain that claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Jan. 23, 2007

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